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EXAMINER	
GUDIBANDE, SATYANARAYAN R	
ART UNIT	PAPER NUMBER
1654	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,023	POULIQUEN ET AL.	
	Examiner	Art Unit	
	SATYANARAYANA R. GUDIBANDE	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 August 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-34* is/are pending in the application.

4a) Of the above claim(s) *8,27 and 30-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-7,9-26,28,29,35 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/1/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group I (claims 1-26, 28 and 29), election of IFN as the active principle (AP), alpha-L-polyglutamate as biodegradable polymer (PO), alpha-tocopherol as the hydrophobic group (HG) in the reply filed on 8/19/09 and election of formula I with R^1 = H, R^2 = H, R^3 = amine cation, R^4 = a direct bond and A = $-CH_2-CH_2-$ in the reply filed on 3/24/10 is acknowledged. The traversal arguments were answered in the non-final action dated 5/25/10.

Status of the pending claims

Applicant's amendment to claims in the response filed on 8/11/10 has been acknowledged.

Claims 1, 3-34 are pending.

Claims 35 and 36 have been added as new claims.

Claims 27 and 30-34 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 8/19/09.

Claim 8 has been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8/19/09.

Claims 1, 3-7, 9-26, 28, 29, 35 and 36 are examined on the merit.

Any objections and/or rejections made in the previous office action dated 5/25/10 and not specifically discussed below in its original or modified form here are considered withdrawn.

Maintained Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-7, 9-26, 28, 29, 35 and 36 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection has been modified to reflect current amendments made to the claims. Response to applicant's arguments appear at the end of the modified rejection.

Regarding claim 1, the phrase "such as" or "such that" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 1 as presented recite a limitation "the concentration of [PO] is **such that** [PO]≥0.9.Cl, where Cl is the "induced gelling" concentration of the particles of PO, as measured in an IG test, **making it possible** to prolong and control the in vivo release time of the AP beyond 24 hours after administration". It is unclear from the claim as recited whether one of ordinary skill in the art would be able to determine the concentration of the PO required for preparing the liquid formulation of the instant invention using the instant specification. The term 'IG test' is not an art recognized term. The specification has the following procedure for the

describing the 'IG test': "The concentration C1 is determined by preparing colloidal formulations having variable concentrations of **amphiphilic polymer** according to the invention and a constant concentration of **therapeutic protein**. To this end, increasing amounts of **dry powdered polymer** are dissolved in deionized water. The solutions are kept at 25°C for 16 hours, with magnetic stirring, before being mixed with a concentrated solution of **therapeutic protein**. The volume and concentration of this solution of **therapeutic protein** are adjusted to give the desired protein concentration for the formulation [for example 0.3 mg/ml of interferon alpha 2b or 2.5 mg/ml of interleukin 2 (IL2)]. The colloidal formulations prepared in this way are mixed with a concentrated aqueous solution of **bovine serum albumin (BSA)** containing 30 mg/ml, and then centrifuged for 15 minutes at 3000 rpm. The mixtures are stirred gently for 24 h and then recovered for characterization". The procedure for 'IG test' relates to using different polymers such as **amphiphilic polymer** and **dry powdered polymer,** and different proteins such as **therapeutic protein** and **bovine serum albumin (BSA)**. Hence it is unclear from the specification how one of ordinary skill in the art would be able to determine the concentration of the PO '**such that**' [PO]≥0.9.Cl and '**making it possible**' to prolong the in vivo release time of AP beyond 24 h after administration.

Claim 1 is drawn to 'A liquid pharmaceutical formulation'. Claim 1 as currently amended further recite that "said formulation is liquid under injection conditions" and "said formulation is liquid at the physiological temperature and at the physiological pH…". It is unclear from the claim as recited whether the applicants are referring to the 'A liquid pharmaceutical formulation' or 'some other formulation' that is 'liquid under injection conditions' and 'liquid at the physiological temperature and at the physiological pH…'.

Claim 17-20 recites the limitation "at least one graft of the polyalkylene glycol type bonded to a glutamate or an aspartate unit" in lines 2 and 3. There is insufficient antecedent basis for this limitation in the claim. The claim **6** from which claims 17-20 depend from recites limitations limited to polyamino acid formed of aspartic units, glutamic units or both aspartic units and glutamic units and does not recite that 'polyalkylene glycol' of claim 17-20.

Claim 10 recites a limitation 'or at least one' at the end of the claim. The claim as recited is incomplete because it does not recite 'at least one of **what limitation**?'.

Response to Arguments

Applicants state that the claims have been amended to overcome the rejections made in the office action dated 5/25/10.

Applicant's arguments filed 8/11/10 have been fully considered but they are not persuasive. Because, the currently amended claims contains further 35 USC 112, 2nd paragraph issues as illustrated in the modified rejection as set forth above.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 6, 16, 21-23, 25, 26 and 36 remain rejected under 35 U.S.C. 102(b) as being anticipated by Huille (US 6,630,171). The rejection has been modified to reflect the current

amendments to the claims. Response to applicant's arguments appears at the end of the reiterated rejection.

In the instant application applicants claim a liquid pharmaceutical formulation for the prolonged release of active principle (AP) comprising an aqueous colloidal suspension of submicronic particles of water-soluble biodegradable polymer (PO) carrying hydrophobic groups (HG) and at least one AP and exhibits the property of forming gelled deposit *in vivo* when injected parenterally and formulation is a at physiologic pH, temperature and in the presence of physiological electrolyte and at least one surfactant.

Huille discloses a composition comprising particles of amphipathic linear polyamino acids of aspartates and glutamates (instant PO) having mean particle size less than 200 μm, the polyamino acids bear at least one hydrophobic group R^0 (the instant HG) and at least one active principle (AP). Huille further discloses that particles in aqueous medium forms colloidal suspension spontaneously compatible with the pH of the physiological media and capable of releasing the AP in vi vivo under physiological conditions in a sustained and controlled way (claim 1 of Huille). This reads on the instant claims 1, 2, 6 and 21. Huille discloses that the number of amino acid residues is approximately 500 (approximate Mol. wt. is 75,000 with a molecular weight of glutamic acid being 147) (claim 16). This reads on the instant claim 16 where the molecular weight of the PO is between 2000 and 100,000 g/mol. Huille also discloses that the number of amino acid residues is approximately 200 (column 5, line 19) (approximate Mol. wt. is 29,400 with a molecular weight of glutamic acid being 147). This reads on the instant claim 36. Huille discloses that the AP can be selected from the group consisting of protein and/or polypeptides, polysaccharides, nucleic acids and mixtures thereof (claim 27) and interferon

(claim 31). This reads on instant claims 22 and 23 and the elected instantly species of IFN. Huille discloses that the medical compositions preferably administered orally, nasally, vaginally, ocularly, subcutaneously, intravenously, intramuscular, intraperitonial and parenterally (columns 9-10, bridging paragraph). This reads on the instant claim 25 and 26.

Response to Arguments

Applicants argue that the main objective of the instant invention is to find a formulation that has an increased prolonged release time of the active agent that is beyond 24 h after administration in vivo. Applicants also argue that they have discovered a critical concentration of polymer PO greater than 0.9 Cl corresponding to the formation of a gel in the presence of BSA in an IG test. Applicants argue that Huille neither mentions nor suggests that the existence of a critical concentration of above which the release of the active ingredient is beyond 24 h after administration

Applicant's arguments filed 8/11/10 have been fully considered but they are not persuasive. The formulation disclosed by Huille anticipates the instant invention as illustrated in the rejection. Although, Huille does not disclose the critical concentration of the PO that impart the extended release time of active ingredient in vivo beyond 24 h, the reference of Huille discloses that the composition disclosed in their work is for releasing the active principle (AP) in vivo under physiological conditions in a sustained and controlled way (claim 1 of Huille). With regards to applicants argument that they have discovered a critical concentration of polymer PO greater than 0.9 Cl corresponding to the formation of a gel in the presence of BSA in an IG test, it should be noted that the aspect of BSA is not present in the instant claims and applicants

appears to be importing limitations from specification that are not present in the instant claims. "Though understanding the claim language may be aided by explanations contained in the written description, it is important not to import into a claim limitations that are not part of the claim. For example, a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment" (See MPEP 2111.01). Also with regards to applicants claim that they invented the 'IG test' to determine the critical concentration of the polymer to impart the property of extended release of AP in vivo, it should noted that this property appears to be inherent in the composition that is anticipated by the prior art of Huille. Moreover, the limitation [PO]≥0.9.Cl is not an art recognized limitation. Also, please note, since the Office does not have the facilities for examining and comparing Applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. *See In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980), and "as a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 3 are rejected under 35 U.S.C. 102(e) as being anticipated by Lambert (US 7030155).

In the instant application applicants claim a liquid pharmaceutical formulation for the prolonged release of active principle (AP) comprising an aqueous colloidal suspension of submicronic particles of water-soluble biodegradable polymer (PO) carrying hydrophobic groups (HG) and at least one AP and exhibits the property of forming gelled deposit *in vivo* when injected parenterally and formulation is a at physiologic pH, temperature and in the presence of physiological electrolyte and at least one surfactant.

Lambert discloses an emulsion vehicle for poorly soluble drugs (AP) and discloses a conjugate of vitamin E derivative (tocopherol) comprising a peptide bonded polyglutamate attached to the ring hydroxyl and pegylated phytosterol (column 8, lines 27-32). The tocopherol being the hydrophobic (HG) of the instant application, the polyglutamate is the PO of the instant invention and phytosterol being the AP. Since Lambert discloses the emulsion composition of the instant invention, it is inherent that it possesses the properties of the instant invention such as 'forming gelled deposit *in vivo* when injected parenterally and formulation is at physiologic pH, temperature and in the presence of physiological electrolyte and at least one surfactant'.

Response to Arguments

Applicants argue that the prior art of Lambert discloses one molecule of alpha-tocopherol residue per molecule of polyglutamate and the currently amended claim 1 of instant invention requires polymer [PO] which **can** carry several hydrophobic groups. Applicants further argue that in the prior art of Lambert, the hydrophobic groups are grafted only at the chain end unlike in the instant invention where the hydrophobic groups are grafted on the side chains of the

polymer. Applicants also argue that the prior art of Lambert does not anticipate the limitation of the critical concentration of 0.9 Cl in an IG test.

Applicant's arguments filed 8/11/10 have been fully considered but they are not persuasive. Applicants are arguing that the polyglutamate of the prior art is different from the polyglutamate of the instant application by stating that the polyglutamate of the prior art is not capable of carrying more hydrophobic moieties. The instant claim only recites 'water soluble polymer [PO] carrying hydrophobic groups'. The claims as presented does not recite that the polymer is carrying multiple hydrophobic groups. As stated by the applicants, the polyglutamic acid of the instant application and the prior art of Lambert '**can**' carry multiple hydrophobic groups. With regards to applicants argument that Lambert does not anticipate the critical concentration of 0.9 Cl in an IG test. It should be noted that the limitation is not an art recognized term. Also, it should be noted that, since the Office does not have the facilities for examining and comparing Applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. *See In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980), and "as a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-7, 12-16, 21-23, 28, 29, 35 and 36 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-7, 12-

16, 21-23, 28, 29 and 35 of copending Application No. 10/580,037. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending Application No. 10/580,037 is drawn to interferon a species of the genus active principle of instant invention. According to MPEP section 2131.02 [R-6], "A generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus." The species in that case will anticipate the genus. Hence the claims of the copending Application No. 10/580,037 anticipate the instant invention.

2. Claims 1-7, 12-16, 21-23, 28 and 29 provisionally remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3, 5, 7, 12-15 and 20-26 of copending Application No. 10/580,035. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending Application No. 10/580,035 is drawn to interleukin a species of the genus active principle of instant invention. According to MPEP section 2131.02 [R-6], "A generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus." The species in that case will anticipate the genus. Hence the claims of the copending Application No. 10/580,037 anticipate the instant invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicants argue that the copending applications have the same priority date and hence cannot anticipate or render obvious the amended claims.

Applicant's arguments filed 8/11/10 have been fully considered but they are not persuasive. The copending U.S. applications 10/580,035 and 10/580,037 having the same priority date have no bearing on the double patenting rejections. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s).

3. Claims 1, 3, 6, 7, 12-16, 21-26, 28, 29, 35 and 36 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 and 15-22 of U.S. Patent No. 7,683,024.

In the instant application applicants claim a liquid pharmaceutical formulation for the prolonged release of active principle (AP) comprising an aqueous colloidal suspension of submicronic particles of water-soluble biodegradable polymer (PO) carrying hydrophobic groups (HG) and at least one AP and exhibits the property of forming gelled deposit *in vivo* when injected parenterally and formulation is a at physiologic pH, temperature and in the presence of physiological electrolyte and at least one surfactant.

Chan discloses a composition comprising a polyamino acid (claim 15 of Chan) wherein the polyamino acid (PO of instant invention) comprises of aspartic or glutamic amino acid residues further comprises at least one alpha-tocopherol (instantly claimed HG) (claim 1 of Chan). The composition also comprises at least one active principle (as recited in claim 16 of Chan) and the composition is a colloidal suspension nanoparticles and/or microparticles in an aqueous phase (claim 20 of Chan). This reads on the instant claims 1, 3, 6 and 28. Chan (claim 22) discloses that the injection of composition is capable of forming a deposit at the site of the injection. This reads on the instant claim 2. The general formula of the claim 2 of Chan reads on the formula I of instant claim 7. Chan also discloses that the PO of the invention comprised of L-glutamate homopolymer (claim 6 of Chan) or comprised of L-aspartate homopolymer (claim 7 of Chan) or comprised of L-glutamate/ L-aspartate homopolymer or vice versa (claim 8 of Chan). This reads on the instant claims 12-15. Chan discloses that molar mass of the polyamino acid to be between 2000 and 100,000 g/mol and preferably between 5000 and 40,000 g/mol ([0065] and claim 9). This reads on the instant claim 16. Chan discloses that the composition may be administered via orally, nasally, vaginally, ocularly, subcutaneously, intravenously, intramuscular, intraperitonial, parenterally or buccal route (claims 21 and 23 of Chan). This reads on the instant claims 25 and 26. Chan discloses that the composition is in the form of a gel, an emulsion, a solution, micelles, microparticles or a powder (claim 20 of Chan). This reads on the instant claim 29.

Chan discloses that greater than 95% association of insulin with the polymer [0139]. However, Chan does not explicitly disclose that the degree of association, i.e., concentration of AP not associated with the polymer is $\leq$1%, as recited in instant claim 24.

It would have been obvious one of ordinary skill in the art improve the % of non-associated AP with polymer to be ≤1% as Chan has taught the association of AP with the polymer is >95%. MPEP section 2144.05 states that "[G]enerally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." Additionally, "[T]he normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." Hence one of ordinary skill in the art would be motivated to optimize the % of association to increase the efficacy of the composition and reduce the cost of the reagent as less non-associated AP molecules are present in the formulation. A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned applications and/or US Patent, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Response to Arguments

Applicants argue that Chan is not available as prior art under 102 and thus Chan can neither anticipate nor render the amended claims obvious. Applicants also argue that the broad claim of Chan does not require submicronic particles of water soluble biodegradable polymer (PO) carrying hydrophobic groups (HG) wherein the concentration of (PO) is such that $[PO] \geq 0.9.Cl$.

Applicant's arguments filed 8/11/10 have been fully considered but they are not persuasive. Claim 20 of Chan as stated in the afore-illustrated rejection clearly recites that the

composition is a colloidal suspension of nanoparticles and/or microparticles and/or micelles of polyamino acids. With regards to applicants argument that Chan is not available as prior art under 102, it should be noted that the priority does not have no bearing on the double patenting rejection. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SATYANARAYANA R. GUDIBANDE/
Examiner, Art Unit 1654

/Cecilia Tsang/
Supervisory Patent Examiner, Art Unit 1654